

PROCEDURES AND POLICIES FOR DEPOSITION OF MICROORGANISMS FOR PATENT PURPOSES IN THE AGRICULTURAL RESEARCH SERVICE CULTURE COLLECTION (NRRL)

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The Agricultural Research Service Culture Collection (NRRL) serves as an international depository for microorganisms that are the subject of patent applications. On January 31, 1981, this depository became an International Depository Authority, thereby offering depositors the option of depositing strains under the Budapest Treaty. An advantage of strain deposit under the Budapest Treaty is that a single deposit is validly recognized in all countries that are signatories of the Treaty, precluding the need for additional deposits if the strains are the subject of patent applications filed in more than one signatory country.

A user fee of \$670.00 is charged for each patent strain deposited with the Agricultural Research Service Culture Collection. Payment may be made at the time of culture deposit or an invoice will be sent to the depositor's institution. Checks for user fees must be for the exact amount in U.S. dollars and should be made payable to: Agricultural Research Service, U.S. Department of Agriculture. This is a one-time fee and includes preservation, storage, initial and periodic viability testing, and all required correspondence.

As soon as the microorganism has been received and proven viable, an NRRL number will be assigned and will be communicated verbally to the depositor upon his request and in writing upon receipt of the deposit fee. The depositor should allow sufficient time for viability testing by the depository before the NRRL number can be received.

BUDAPEST TREATY DEPOSITS

In order for strains to be deposited under the Budapest Treaty, a signed Budapest Treaty

Deposition Form must accompany each deposit. Forms can be obtained from the Curator of the Patent Collection or downloaded from the ARS Culture Collection Website at <http://nrml.ncaur.usda.gov>.

When strains are to be deposited under the Budapest Treaty, the International Receipt Form (BP/4) will be issued and sent upon receipt of the following: (1) a viable microorganism, (2) the completed Deposition Form, and (3) the correct fee. The Viability Statement will be sent as soon as the depository's preparation is also determined to be viable. At the same time, the depository's preparation will be sent to the depositor so that the depositor can determine its equivalency to the original deposit. The depositor then completes the Viability Statement and returns it to the Agricultural Research Service Culture Collection.

If the depositor elects not to confirm the equivalency of the Agricultural Research Service Culture Collection's preparation to his deposit (this is permitted under the Budapest Treaty), this information will be communicated to authorized requesters at the time the microorganism is distributed.

If the depository's preparation is found not equivalent (does not correspond to, or function as, the microorganism described in the patent application), a replacement culture must be sent accompanied with the form "Statement in the Case of a New Deposit." A new set of preparations will be made and a "Receipt in the Case of a New Deposit" will be issued by the depository and sent to the depositor for verification of equivalency.

The Agricultural Research Service Patent Culture Collection (NRRL) does not issue a

catalog or place any patent strains on the NRRL on-line catalog. It has no regulations imposing restrictions on the use of progeny of strains deposited for patent purposes. Such materials are distributed according to the depositor's wishes so long as there is no adverse effect on Agricultural Research Service Culture Collection (NRRL) policies. The depositor's wishes generally are based on interpretation of patent office requirements. Use of such materials, once distributed, is the responsibility of the requestor. Strains are automatically removed from any restriction category once a patent issues wherein the particular microorganism is disclosed. The Requesters are advised, at the time the material is sent, that any commercial or other unauthorized use of these strains without the consent of the depositor could involve patent infringements

Strains of microorganisms deposited in the Agricultural Research Service Culture Collection (NRRL) under the Budapest Treaty will be maintained with all the care necessary to keep them viable and uncontaminated for a period of not less than 30 years from the date of deposit. In addition thereto, the strain will be stored for a period of at least 5 years after the most recent request for the release of a sample.

KINDS OF MICROORGANISMS ACCEPTED FOR DEPOSIT FOR THE PURPOSES OF PATENT PROCEDURE

1. The Agricultural Research Service Culture Collection (NRRL) is willing to accept for deposit, in connection with patent applications, progeny of strains of agriculturally and industrially important bacteria, yeasts, molds, and *Actinomycetales*, **EXCEPT**:

- a. *Actinobacillus* (all species)
Actinomyces
(anaerobic/microaerophilic, all species)
Arizona (all species)
Bacillus anthracis
Bartonella (all species)

Bordetella (all species)
Borrelia (all species)
Brucella (all species)
Burkholderia mallei (*Pseudomonas mallei*)
Burkholderia pseudomallei
(*Pseudomonas pseudomallei*)
Clostridium botulinum
Clostridium chauvoei
Clostridium haemolyticum
Clostridium histolyticum
Clostridium novyi
Clostridium septicum
Clostridium tetani *Corynebacterium diphtheriae* *Corynebacterium equi*
Corynebacterium haemolyticum
Corynebacterium pseudotuberculosis
Corynebacterium pyogenes
Corynebacterium renale
Diplococcus (all species)
Erysipelothrix (all species)
Haemophilus (all species)
Francisella (all species)
Herellea (all species)
Klebsiella (all species)
Leptospira (all species)
Mima (all species)
Moraxella (all species)
Mycobacterium avium
Mycobacterium bovis
Mycobacterium tuberculosis
Mycoplasma (all species)
Neisseria (all species) *Pasteurella* (all species)
Sphaerophorus (all species)
Streptobacillus (all species)
Streptococcus (all pathogenic species)
Treponema (all species)
Vibrio (all species)
Yersinia (all species)

- b. *Blastomyces* (all species)
Coccidioides (all species)
Cryptococcus gattii (*Filobasidiella bacillispora*)
Cryptococcus neoformans
(*Filobasidiella neoformans*)
Histoplasma (all species)

Paracoccidioides (all species)

- c. All viral, Rickettsial, and Chlamydial agents.
 - d. Agents which may introduce or disseminate any contagious or infectious disease of animals, humans, or poultry and which would require a permit for entry and/or distribution within the United States of America.
 - e. Mixtures of microorganisms.
 - f. Fastidious microorganisms that would require (in the view of the Curator) more than reasonable attention in handling and preparation of lyophilized material.
 - g. Phages not inserted in microorganisms.
 - h. Monoclonal antibodies.
 - i. All cell lines.
 - j. Plasmids or other nucleic acid sequences not inserted in microorganisms.
 - k. All select agents.
2. Recombinant strains of microorganisms, strains containing recombinant DNA molecules, strains containing their own naturally occurring plasmid(s), strains containing inserted naturally occurring plasmid(s) from another host, strains containing inserted constructed plasmid(s), and strains containing viruses of any kind (excluding those already listed as nonacceptable) will be accepted only if the deposit document accompanying the microbial preparation(s) includes a clear statement that progeny of the strain(s) can be processed at a Physical Containment Level of no greater than BSL-2 and Biological Containment requirements meet all other criteria specified by the U.S. Department of Health and Human

Services, National Institutes of Health; "Guidelines for Research Involving Recombinant DNA Molecules, December 1978" (Federal Register, Vol. 43, No. 247--Friday, December 22, 1978) and any subsequent revisions.

3. Agents which are classified as Plant Pests require a permit for entry and/or distribution within the United States of America.

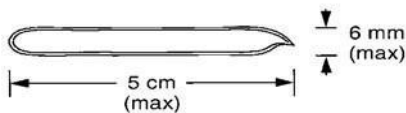
Curators in the Agricultural Research Service Culture Collection (NRRL) do not attempt to make identification or to name any organism that has been deposited in connection with a patent application, nor do they carry out research work with such deposits until a U.S. Patent issues or cultures are otherwise released. It is not necessary, of course, to provide a precise identification but the depositor should state to which genus the microorganism belongs. If special media or conditions are required for growth and maintenance, such information should be supplied. We now recommend that two agar slant cultures or two lyophilized preparations for each strain be received from depositors. **As stated in the Budapest Treaty, depositors are responsible for resupplying material should the need ever arise and this responsibility extends beyond the life of the patent.**

The depositor has the option of sending materials for deposit to the Agricultural Research Service Culture Collection (NRRL) in three ways:

1. Two agar slant cultures of the microorganism(s) growing on an appropriate medium. Sufficient material is prepared by our curators to make 30 lyophilized preparations, check one for viability and distribute the remainder as in options 2 and 3. If initial agar slant cultures deposited appear suitable, lyophilizations often are made from that material. If cultures fail to lyophilize, they will be stored frozen in the vapor phase of a liquid

nitrogen freezer.

2. Two lyophilized preparations, clearly labeled with the depositor's original strain designation. On receipt, the microorganism is cultivated on appropriate agar media and 30 lyophilized preparations are made. One of these is checked for viability, the remainder handled as in option 1. This option, and option 3, below, are acceptable provided cultures submitted are not fastidious and do not require more than usual normal growth procedures.
3. Thirty lyophilized preparations, clearly labeled with the depositor's original strain designation and date the tubes were sealed (month, day, year) and in tubes of **no greater dimensions than indicated in the drawings below:**



One of these is tested for viability, the NRRL number is placed on each tube, and the supply of tubes stored at 3°C to 5°C. *Bona fide* letter requests for progeny would be shipped from this stock.

Larger sized tubes greatly complicate storage. If the preceding specifications cannot be met, please contact the Curator to make sure your preparations will be accepted before they are sent.

ADDITIONAL COMMENTS

1. The Agricultural Research Service Culture Collection (NRRL) reserves the right to refuse to accept for deposit any microorganism which, in its opinion, is dangerous or impossible to maintain in its

collection.

2. Every effort is made to comply with existing laws, rules, and regulations, although the Agricultural Research Service Culture Collection (NRRL) accepts **no** responsibility for violation of any import, export, or other laws, rules, or regulations governing shipment of progeny of strains of microorganisms to or from any location in the world.
3. Progeny of strains deposited in, and accepted by, the Agricultural Research Service Culture Collection (NRRL) cannot be returned to depositor *in toto* or completely destroyed except for very good reason, e.g., the receipt and accessioning of a virulent pathogen by mistake. In addition, under the Budapest Treaty, the depositor must sign the Budapest Treaty Deposition Form in which it is agreed that the strain will not be withdrawn for the period specified by Rule 9 of the Budapest Treaty (at least 30 years from the date of accessioning).
4. Progeny (agar slant cultures or lyophilized preparations) of strains of microorganisms deposited in connection with patent applications may be obtained (when restrictions, if any, are removed), by a letter of request stating the name of the microorganism and its strain number (our NRRL number) or by providing an otherwise satisfactory reference to the strain(s) in question. A \$40 fee is charged for all patent strains.
5. The depositary will notify the depositor when strains are distributed to third parties only when the strain has been deposited under the Budapest Treaty. The depositor will receive a copy of the request and the International Form BP/14 "Notification of

the Furnishing of Samples of Deposited Microorganisms.” **No notification** will be sent to depositors of strains not deposited under the Budapest Treaty. If the depositor requires information on who has received a culture, the depositor may, from time to time, request this information, as is necessary.

6. The Agricultural Research Service Culture Collection (NRRL) has been recognized as an International Depositary by the European Patent Organization. A letter of instructions stating that the deposit(s) is (are) subject to Rule 28 of the European Patent Organization must accompany the deposit(s) in order that the European Patent Organization can authorize the distribution of the strain(s). If the strain is deposited under the Budapest Treaty, this statement is not necessary.

CONTACT INFORMATION:

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